Digi-X
Digital IT Ubiquitous System

K092772

Exhibit 5 510(k) Summary

Portable X-Ray System / Model: HAND-RAY

JAN - 6 2010

1. Submitter and US Official Correspondent

Submitter:	Hanjin Digi-X Co., Ltd.
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	470-5, Gasan-dong, Geumcheon-gu
	Seoul, 153-789, Korea
Official Correspondent:	Shin Kuk Yoo, Consultant
Telephone No.:	714-313-7442
Fax No.:	801-303-7455
Email:	skyone@LSKBioPartners.com

2. Establishment Registration Number The firm will be registered and listed prior to distribution of medical device.

3. Device Information

Proprietary/Trade Name:	Portable X-Ray System (Model: HAND-RAY)
Common/Usual Name:	Portable X-Ray System
Classification Name:	Extraoral Source X-Ray System
Product Code:	EHD
Device Class:	Class II per regulation 21 CFR 872.1800

4. Equivalent Legally Marketed Device

Predicate #1

Manufacturer:	GENORAY Co., Ltd.
Device Name:	Portable X-Ray System (Model: PORT-X II)
510(k) Number:	K063121 (Decision Date – Jan. 11, 2007)
Classification:	Extraoral Source X-Ray System: EHD, Class II per regulation 21 CFR 872.1800

Predicate #2

Manufacturer:	DIGIMED Co., Ltd.
Device Name:	Portable X-Ray System (Model: DIOX-602)
510(k) Number:	K082167 (Decision Date – Sep. 26, 2008)
Classification:	Extraoral Source X-Ray System: EHD, Class II per regulation 21 CFR 872.1800

5. Description of the Device

The Portable X-ray System (Model: HAND-RAY) is portable dental X-ray system that operates on 24VDC supplied by a rechargeable Li-Polymer battery pack. The X-ray controls and power source are assembled into a single hand-held enclosure. The package includes battery charger.

The Portable X-ray System generates and controls X-ray in order to diagnose of tooth and jaw. It is composed of X-ray generator, controller and beam limiting device. Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates tooth and jaw, and makes X-ray images on receptor (chemical film or digital sensor).

The Portable X-ray System (Model: HAND-RAY) is a diagnostic x-ray system, which is intended to be used by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors.

Its use is intended for both adult and pediatric subjects. This device includes a high frequency inverter that changes direct current to alternating current, X-ray tube, electrical protective devices, and other elements. The portable X-ray system (Model: HAND-RAY) provides with sharp and clear images and keeps patients and dentists away from radiation using small dose of radiation.

6. Indications for use

The portable X-ray system (Model: HAND-RAY) is intended to be used by trained dentists and dental technicians as extraoral X-ray source for producing diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

7. Safety, EMC and Performance Data

The compliance of HAND-RAY will satisfy the applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32. All required documents and reports will be submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

EMC test was performed by SGS Testing Korea Co., Ltd. for HAND-RAY in accordance with Standard EN/IEC 60601-1-2. All test results were complied with the requirements.

8. Safety and Effectiveness, comparison to Predicate

The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

9. Substantial Equivalence Chart

Company name	Hanjin Digi-X Co.	GENORAY Co.	DIGIMED Corp.
Model	HAND-RAY	PORT-X II	DIOX-602
510(k) No	New	K063121	K082167
Energy Source	Rechargeable 24V, DC Lithium polymer battery pack	Rechargeable 22.2V DC Lithium polymer battery pack	Rechargeable 24V, DC Lithium polymer battery pack
Expose time	0.02 ~1.8 seconds, 0.01 sec. increments	0.01~2.0 seconds 0.01 increments	0.01-1.6 seconds, 0.01 increments
Time accuracy	±(10% +1ms)	±(10% +1ms)	±(10% +1ms)
mA	2mA fixed	2mA fixed	2mA fixed
kVp	60kV fixed	60kV fixed	60kV fixed
Wave form	Constant Potential(DC)	Constant Potential(DC)	Constant Potential(DC)
Safety, EMC and performance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32
Source to skin distance	20cm	20 cm	20cm
Cone diameter	6cm	7 cm	6.5 cm
User Interface	Exposure time: up, down selection of parts of teeth, adult and child, film and sensor with display	Exposure time: up, down Selection buttons of parts of teeth, adult and child, film and sensor with display	Exposure time: up, down Two buttons for modes and selection of parts of teeth, adult and child, film and sensor with display
Exposure switch	Control panel and remote controller	Control panel and remote controller	Control panel and remote controller
Tube head mounting	Yes	Yes	Yes
Intended use	Intended to use by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors. Its use is intended for both adult and pediatric subjects.		

10. Conclusion

In reference to the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807 and the comparison information provided substantial equivalent chart above, the Hanjin Digi-X Co., Ltd., believes that the portable X-ray system (Model: HAND-RAY) is safe and effective and substantially equivalent to the predicate devices, PORT-X II and DIOX-602.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Hanjin Digi-X Co., Ltd.
% Mr. Shin Kuk Yoo
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LSK BioPartners, Inc.
215 S. Street, Ste 100B
SALT LAKE CITY UT 84111

JAN - 6 2010

Re: K092772
Trade/Device Name: Portable X-Ray System (Model: Hand-Ray)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: November 27, 2009
Received: December 2, 2009

Dear Mr. Shin Kuk Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit 4 **Indications for Use**

510(k) number (if known): K092772

Device Name: Portable X-Ray System (Model: HAND-RAY)

Indications for Use:

The Portable X-ray System (Model: HAND-RAY) is intended to be used by trained dentists and dental technicians as extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092772